EXHIBIT C

Edward J Stanford MD MS FACOG FACS
Current Address :
[redacted]

Phone: [redacted]

Dr. Edward Stanford is a Board Certified/Recertified Obstetrician/Gynecologist. His practice is nationally and internationally recognized in the areas of incontinence, interstitial cystitis and bladder disorders, chronic pelvic pain, prolapse surgery, laparoscopy and minimally invasive pelvic surgery, mesh and graft technology, fistula surgery, urodynamic testing, and complications of pelvic surgery. Dr. Stanford has served on the faculty of the University of Tennessee, Memphis as Professor of Obstetrics and Gynecology, Division Head of Gynecologic Services, Chief of Urogynecology/Female Pelvic Medicine, Chief of Ambulatory Services, and Fellowship Director of Minimally Invasive Gynecologic Surgery and UCLA as volunteer clinical faculty for the Urogynecology Fellowship. Dr. Stanford serves as the Chairman of the Fistula Subcommittee of the International Urogynecologic Association and as an advisor to the UNFPA and the WHO in the area of Fistula surgery and research.

Dr. Stanford is actively involved with many Gynecologic societies including the Society of Gynecologic Surgeons (SGS) (Membership Committee 2008-2011), the American Urogynecologic Society (AUGS) (Executive Committee Member 1999-2002, Chair, Coding and Nomenclature Committee 1999-2002), the American College of Obstetrics and Gynecology (ACOG) (Coding and Nomenclature Committee 1999-2006), the American Association of Gynecologic Laparoscopists (AAGL) (Coding Committee 2000-2008, Board of Trustees (2009-2011), the International Pelvic Pain Society (IPPS), the International Continence Society (ICS) (Ethics Committee 2007, 2009-2011, School of Urodynamics 2009-2010, Urodynamics Committee 2010-present), the International Urogynecologic Association (IUGA) (Research and Development Commttee 2006-present, Chair, Fistula Subcommittee 2007-present, Public Relations Committee 2007-2011), American Association of Urologists (Coding Committee 1999-2002), American College of Surgeons (2004-present), Memphis Robotic Surgery Society (Treasurer 2009-2010), and the International Society of Fistula Surgeons (ISOFS).

Dr. Stanford is a reviewer for several Gynecologic and Urologic journals: British Journal of Obstetrics and Gynecology, International Journal Obstetrics and Gynecology, Journal of Pelvic Medicine and Surgery (Editorial Board 2002-2010), Obstetrics and Gynecology (green journal), Journal of Minimally Invasive Gynecology (formerly the Journal of the American Association of Gynecologic Laparoscopists) (Editorial Advisor 2000-2009; Editorial Board 2009 – present), American Journal of Obstetrics and Gynecology (gray journal), Urology Journal (gold journal), International Urogynecologic Journal and Pelvic Reconstructive Surgery, Journal of Robotic Surgery (Editorial Consultant 2010 – present). Dr. Stanford has authored 15 textbook chapters. He has been the principal investigator on several studies involving interstitial cystitis and pelvic reconstructive surgery trials.

Dr. Stanford received his B.A. from Pepperdine University in 1979, his M.S. from University of California, Los Angeles (UCLA) in 1983, and his M.D. from the Medical College of Pennsylvania in 1985. His training included an internship in General Surgery

at Cedars-Sinai Medical Center in Los Angeles 1985-1986, residency in Family Medicine at Northridge Hospital and Medical Center (UCLA affiliate) 1986-1989, and a residency in Obstetrics and Gynecology at Illinois Masonic Medical Center in Chicago 1990-1993.

Legal Work Prices

Retainer: $2,500

Review of records - medical records, transcripts, telephone calls, correspondence, and preparation of reports

- $500/hour (15 minute intervals)

Meetings/Testimony or trial appearance -

- $8,000/day (> 3 hour, includes travel time)
- Plus travel expenses

Overnight travel

- $2,500 plus expenses

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: *Non-Revision PTOS 293, 298 (Election Wave)*	

GENERAL EXPERT REPORT OF EDWARD STANFORD, M.D.

General Report on TVT Products

Edward Stanford, MD

I am a board-certified Obstetrician Gynecologist with extensive experience in Female Pelvic Medicine and Reconstructive Surgery. I am licensed to practice in California, Colorado, and Washington. I have served on the faculty of the University of Tennessee as a full Professor in the Department of Obstetrics and Gynecology, Division Chief of Gynecologic Specialties, Chief of Urogynecology, Chief of Ambulatory Services, Director of Benign Gynecology, and the Fellowship Director of Minimally Invasive Gynecologic Surgery. I have also served on the Urogynecology faculty at the University of California, Los Angeles.

I graduated with my Doctor of Medicine from the Medical College of Pennsylvania in Philadelphia, PA in 1985. My internship was in General Surgery at Cedars Sinai Medical Center in Los Angeles, CA after which I completed a residency in Family Medicine from UCLA program at Northridge Hospital and Medical Center in Northridge, CA and obtained Board Certification. I went on the complete my residency training in Obstetrics and Gynecology at Illinois Masonic Medical in Chicago, Illinois and obtained Board Certification.

My career has included academic practice and private clinical practice. I have also consulted to several international organizations including the World Health Organization (WHO), the UNFPA, and Harvard Humanitarian primarily performing surgery, teaching and training medical students, residents, and fellow surgeons from the US, Africa, and Europe in the field of vesicovaginal fistulae. I have been certified by the International Society of Fistula Surgeons (ISOFS) as an expert in complex fistula surgery. My consulting has allowed to perform surgery in approximately 30 countries. In recognition of my work in this field I was honored with the Violet Bowen Women's Awareness Humanitarian Award in 2010.

I have multiple peer-reviewed publications in the area of female pelvic conditions, complex pelvic surgery including mesh implant procedures, various gynecologic disorders, and pelvic pain. I review peer reviewed manuscripts for multiple journals. I have served as an editor of the Journal of Minimally Invasive Gynecology, the Female Pelvic Medicine and Reconstructive Surgery journal, the Journal of Robotic Surgery, and the International Urogynecology Journal. I have been active in leadership of several gynecologic surgery societies. For the American Association of Gynecologic Laparoscopists (AAGL), I have served on the Board of Directors and Chaired the Coding Committee. I have been a member of their video and abstract review committees, the Urogynecology Special Interest Group, and the Endometriosis Classification Task Force. I have been a member of the Executive Committee of the American Urogynecologic Society (AUGS).

I have been trained and have performed the Gynecare TVT mid-urethral procedure since 1999. I have performed well over 2,000 mesh tape procedures to treat female urinary incontinence using various devices from several manufacturers including Gynecare (TVT, TVT-O, TVT Abbrevo, and TVT Secur).

My CV is attached to supplement knowledge of my professional background.

II. Materials Reviewed

In preparation of my opinions I have searched and reviewed the medical and scientific literature concerning the efficacy and safety of TVT primarily those published in peer-reviewed journals or abstracts from scientific meetings. I have also reviewed the Ethicon TVT Instructions for Use, Professional Education materials made available to TVT surgeons, the TVT Surgeons Resource Monograph, and other Ethicon documents. My materials review included analyses from professional societies, systematic reviews, meta-analyses, and professional guidance and statements. A list of these materials and those that I may use at trial are attached to this report. I have also reviewed the Plaintiffs' expert reports and the materials cited by Plaintiffs' experts.

III. Fees and Expert Testimony

My fees for serving as an expert in this matter are: $500/hour for review, report drafting and meetings and $8,000/day for deposition and trial testimony.

IV. Opinions

My opinions in this general report are based upon my education, training, clinical research, my experience teaching students, residents, and fellow surgeons, and my professional experience. I attempt to base my opinions on facts supported by my interpretation of published medical literature whenever possible. I also base my opinions the knowledge I have gained from performing surgery and my clinical experience with the diagnosis, testing, and management of simple, complex, and recurrent urinary incontinence. All of my opinions are held to a reasonable degree of medical and scientific certainty. My opinion is that the TVT devices are reasonably safe for its intended use. It is the most studied mid-urethral sling procedure in medical history and no other design or mesh sling procedure has been found to be more effective or safer. The professional educational materials, the Surgeon's Monograph, and the TVT IFUs are adequate to warn of the risks of the TVT devices.

Urinary incontinence – pathophysiology

Stress urinary incontinence (SUI) in adult women has an observed prevalence between 4% and 35%[1] and up to 4-10% of US women are estimated to have anti-incontinence surgery.[2] Female SUI can be debilitating that can markedly reduce the woman's psychological well-being and quality of life. The financial burden in the US is 20 billion dollars annually.[3] [4]

Traditional anti-incontinence procedures are based upon older theories regarding the pathophysiology behind stress urinary incontinence. These theories focused on the pressure transmission between the increased abdominal pressure (i.e. during a cough or sneeze) and a

[1] Luber KM. The definition, prevalence, and risk factors for stress urinary incontinence. Rev Urol. 2004;6 (suppl 3):S3-9.
[2] Albo ME et al. Burch colposuspension versus fascial sling to reduce urinary incontinence. NEJM. 2007 May;357(14):1457.
[3] Fantl JA et al. Urinary incontinence in adults: Acute and chronic management. Clinical practice guideline, No. 2, 1996 Update (AHCPR Publication No. 96-0682). Rockville, MD: U.S. Department of health and Human Services, Public Health Service Agency for Health Care Policy and Research.

simultaneous reduction in in urethral closure pressure, which results in stress leakage[5] [6] Another theory is the "Integral Theory" proposed by Petros.[7] [8] In this theory, SUI is related to a complex of mid-urethral support from the pubo-urethral ligaments, the pubococcygeous and levator ani muscles. It was a key driving concept in the development of the TVT (originally the intravaginal slingplasty).

History of the TVT - why it is the gold standard for the treatment of female stress urinary incontinence.

A brief review of the history preceding the development of the TVT shows clearly that an alternative surgical method was needed. It has been and continues to be suggested that the initial treatment for female SUI should employ conservative approaches such as Kegel exercises, weight loss, behavior modification, biofeedback, vaginal cone insertion, or pessary insertion. These sometimes work but not predictively. Historically, surgical approaches to treat female SUI have been considered to be a more cost effective first line therapy however the long-term success of these procedures has been poor. The traditional surgical procedures have included several approaches designed to elevate the anterior vagina or bladder neck or to support the mid-urethra. The procedures include endoscopic bladder neck suspension operations (Pereyra, Stamey, Muznai, Gittes, Raz), Marshall-Marchetti-Krantz (MMK), Burch retropubic colposuspensions, pubovaginal slings, periurethral or transurethral bulking injections, and artificial sphincters. The primary reason for so many iterations of surgery to treat SUI is that they were not associated with high long-term success and were invasive procedures. The Burch, MMK, and pubovaginal sling required an abdominal incision with retropubic dissection, required long operating room times, and lengthy hospital stays and recovery times. These include hemorrhage, hematoma, infection, and injury to adjacent anatomic structures.[9] The pubovaginal sling traditionally required fascial dissection either from the rectus abdominal fascia on the abdomen or from the tensor fascia lata on the lateral thigh leading to longer OR times, infections, and increased pain.

Essentially, all anti-incontinence surgical procedures are associated with intraoperative risks and complications. There is a rich history of medical literature describing short-term and long-term complications from these procedures. These include hemorrhage, infection, abscess, pelvic hematoma, urinary tract and visceral injuries, wound infection, osteitis pubis, urogenital fistulae, nerve injuries, voiding dysfunction, delayed or obstructive voiding, detrusor instability, de novo detrusor instability, dyspareunia, chronic groin pain, and worsened quality of life.[10] [11] [12]

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[5] Einhorning G. Simultaneous recording of intravesical and intr0urethral pressure. A study on urethral closure in normal and stress incontinent women. Act Chir Scand Suppl. 1961;Suppl276:1-68.

[6] DeLancey JO. Stuctural support of the urethra as it relates to stress urinary incontinence: the hammock hypothesis. Am J Obstet Gynecol. 1994 Jun;170(6):1713-20.

[7] Petros PE, Ulmsten UI. An integral theory of female urinary incontinence: Experimental and clinical considerations. Acta Obstet Gynecol Scand Suppl. 1990;153:7-31.

[8] Petros PE, Ulmsten UI. An integral theory and its method for the diagnosis and management of female urinary incontinence. Scand J Urol Nephrol Suppl. 1993;153:1-93.

[9] Chaliha, C and Stanton SL. Complications of surgery for genuine stress incontinence. Br J Obstet Gynaecol. 1999 Dec;106:1238-45.

[10] Beck, R.P. & Lai, A.R. Results in treating 88 cases of recurrent urinary stress incontinence with the Oxford fascia lata sling procedure. Am J Obstet Gynecol 142, 649-
51 (1982).

Considering the published success of the invasive pubovaginal sling, the Burch colposuspension, the MMK, and less invasive endoscopic Stamey bladder neck suspension, it becomes evident that the risks and poor long-term success did not outweigh the benefits. There have been several studies looking comparing various anti-incontinence procedures. The New England Journal (2007) published a largest multicenter RCT to date - the SISTEr trial. In that trial a traditional autologous pubovaginal sling was compared to the Burch colposuspension (see Albo et al NEJM 2007). A total of 655 women were followed for 24 months with success defined as no self-reported symptoms of SUI, a negative stress test and no retreatment for SUI. The results showed 66% success for the PV sling versus 49% for the Burch group. Serious adverse events were reported in 13% and 10% of cases, respectively. Wound complications occurred in 25% overall, 4% required surgical re-intervention, and 3% of the patients randomized to a Burch colposuspensions sustained a bladder injury. In the SISTEr trial voiding dysfunction was reported in 14% of women undergoing the pubovaginal sling with 6% requiring surgical revision for persistent voiding dysfunction. Follow up of 5- and 7-years was reported in the E-SISTEr trial.[13] Urinary continence rates from the SISTEr to E-SISTEr studies decreased during a period of 2 to 5 and to 7 years postoperatively from 42% to 24% to 13% in the Burch group and from 52% to 34% to 27% in the sling group, respectively.

Similar to the SISTEr trial, several other studies have shown that the Burch does provide long-term continence. In the study by Demirci, the overall cure rate for the Burch colposuspension was 87.7% at 1.5 years and 77.4% at a mean 4.5 years of follow-up, and the symptom free cure rate declined 83.9% at 3 years, 76.2% at 4 years, 75% at 5 years, and 68% at 6 years.[14] Van Geelen et al. (1988) reported an objective cure rate after 3 months of 100% with a steady decline to 85% at 1-2 years and 75.8% at 5 years.[15] Reports of continence cure show 78.6% cure at 6 years (Thunedborg et al 1990),[16] 78% at 5 years (Kinn 1995),[17] 64% at 5 years (Lebret et al. 1997),[18] 63% at 6 years (Kjolhede and Ryden 1994),[19] and 32% (Christensen et al 1997).[20] It should be understood that the SISTEr randomized study looked at 2 procedures that have largely been abandoned as surgical choices by practicing surgeons and despite being published in a very prestigious journal, is of little clinical utility. A slightly more appropriate randomized study

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[11] Bent AE, Ostergard DR, Zwick-Zaffuto M, "Tissue reaction to expanded polytetrafluoroethylene suburethral sling for urinary incontinence: clinical and histologic study," Am J Obstet Gynecol, vol. 169, no. 5, pp. 1198-204, 1993.
[12] Galloway NT et al. The complications of colposuspensions. Br J Urol. 1987 Aug;60(2):122-4.
[13] Richter HE et al. Patient related factors associated with long-term urinary continence after Burch colposuspensions and pubovaginal fascial sling surgeries. J Urol. 2012 Aug;188(2):485-9.
[14] Demirci F et al. Long-term results of Burch colposuspensions. Gynecol Obstet Invest. 2001;51:243-247.
[15] van Geelen JM et al. The clinical and urodynamic effects of anterior vaginal repair and Burch colposuspensions. Am J Obstet Gynecol. 1988 Jul;159(1):137-44.
[16] Thunedborg P et al. Stress urinary incontinence and posterior bladder suspension defects. Results of vaginal repair versus Burch colposuspensions. Acta Obstet Gynecol Scand. 1990;69(1):55-9.
[17] Kinn AC. Burch colposuspensions for stress urinary incontinence. 5-year results in 153 women. Scand J Urol Nephrol. 1995 Dec;29(4):449-55.
[18] Lebret T et al. Isolated Burch type indirect colposuspension of the bladder neck in the treatment of stress urinary incontinence in women. Long-term results. Prog Urol. 1997 Jun;7(3):426-32.
[19] Kjolhede P, Ryden G. Prognostic factors and long-term results of the Burch colposuspensions. A retrospective study. Acta Obstet Gynecol Scand. 1994 Sep;73(8):642-7.
[20] Christensen H et al. Long-term results of the Stamey bladder-neck suspension procedure and of the Burch colposuspensions. Scand J Urol Nephrol. 1997 Aug;31(4):349-53.

looked at the laparoscopic Burch compared to the TVT.[21] This study reported similar outcomes for both procedures with bothersome SUI symptoms in 11% (Burch) and 8% (TVT) after 4-8 years.

Similarly, the MMK vesicourethropexy showed long-term success of 33% with a 70% incidence of urinary urgency[22] while the Stamey shows equally poor long-term success of 44% (see Clemens et al 1998) and 39% (see Christensen et al 1997).

TVT has improved long-term success compared to traditional surgical approaches
Clearly, an improved method to address the pathophysiology responsible for female SUI that was less invasive, required less hospital resources and recovery time, with improved long-term success was needed. The original TVT publication (intravaginal slingplasty – IVS) described an ambulatory procedure done under local with cystoscopic control.[23] From that introduction the TVT mid-urethral sling with polypropylene mesh support was adopted worldwide, has been extensively studied, and has become the accepted standard and method of choice to surgically treat female SUI. Other companies have adopted the method and alternative surgical approaches such as the transobturator approach have been developed and extensively studied.

Subsequently, numerous long-term studies have been published showing long-term cure of SUI that exceeded the success rates of the preceding surgical methods mentioned above. Examples of some of these long-term successes include Aigmueller et al (2011) showing objective cure at 10 years of 84% with a strongly positive clinical stress test of 4.3%. Eleven percent considered themselves worse.[24] Liapis A, et al (2008) found an objective cure rate after tension-free vaginal tape (TVT) of 83% at 5-years with a very small drop to 80% at 7-years.[25] Nilsson et al (2008) reported 11-year global impression of cure of 77%.[26] Angioli et al (2010) published objective 5-year cure of 71.4% at 5-years compared to 72.9% for the TVT-O.[27] And, Braga et al (2018) recently published 17-year follow-up data showing 91% cure with no perceived decrease overtime.[28]

In 2014, the Society of Gynecologic Surgeons (SGS) conducted a systemic review and meta-analysis of traditional incontinence procedures versus mid-urethral slings. Subjective cure rates

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[21] Jelovsek JE et al. Randomised trial of laparoscopic Burch colposuspensions versus tension-free vaginal tape: long-term follow up. BJOG. 2008(Jan);115(2):219-25.
[22] Clemens JQ et al. Long-term results of the Stamey bladder neck suspension: direct comparison with the Marshall-Marshall-Krantz procedure. J Urol. 1998 Aug;160(2):372-6.
[23] Ulmsten U, Petros P. Intravaginal slingplasty (IVS): an ambulatory surgical procedure for treatment of female urinary incontinence. Scand J Urol Nephrol. 1995 Mar;29(1):75-82.
[24] Aigmueller T, et al. Ten-year follow-up after the tension-free vaginal tape procedure. Am J Obstet Gynecol. 2011;205:496.e1-5.doi: 10.1016/j.ajog.2011.07.010.
[25] Liapis A, Bakas P, Creatsas G. Long-term efficacy of tension-free vaginal tape in the management of stress urinary incontinence in women: efficacy at 5- and 7-year follow-up. Int Urogynecol J Pelvic Floor Dysfunct 2008;19:1509-12.
[26] Nilsson CG et al. Eleven years prospective follow-up of the tension-free vaginal tape procedure for treatment of stress urinary incontinence. Int Urgoynecol J Pelvic Floor Dysfunct. 2008 Aug;19(8):1043-7.
[27] Angioli R, et al. Tension-Free Vaginal Tape Versus Transobturator Suburethral Tape: Five-Year Follow-up Results of a Prospective, Randomised Trial. Eur Urol. 2010;58:Q671-677.
[28] Braga A, et al Tension-free vaginal tape for treatment of pure urodynamic stress urinary incontinence: efficacy and adverse effects at 17-year follow-up. BJU Int. 2018 Jul;122(1):113-117.

were more than 50% lower in the pubovaginal sling group (OR 0.40, 95% CI 0.18-0.85). Based on these results, this august and elite surgical society recommended preferential use of mid-urethral slings for the surgical treatment of SUI.[29] The American Urogynecology Society (AUGS) and the Society of Urodynamics, Female Pelvic Medicine, and Urogenital Reconstruction (SUFU) have stated that the use of polypropylene midurethral slings is not only the recognized worldwide standard of care for the surgical treatment of SUI, but it is safe and effective, and has improved the quality of life for millions of women.[30] Other authors have recognized that the mesh mid-urethral sling has become the preferred method to surgically treat female SUI and have considered it to be the "gold standard".[31] [32]

Complications

No anti-incontinence surgery is void of complications. The same must be said for the tension-free vaginal tape (TVT). Known and published complications of the TVT procedure include bladder perforation, voiding dysfunction, hemorrhage, and bladder, urethral, and vaginal erosions.[33] Complications have been well described in the medical literature, especially the highest level systematic reviews and meta-analyses demonstrating a favorable safety profile for midurethral slings and the TVT devices.[34] Additionally, long-term data reported in the medical literature demonstrates that implantation of TVT is associated with comparable or lower complication rates. The potential risks of foreign body implants in pelvic floor surgery are commonly known to pelvic floor surgeons and have described in the medical literature for decades.[35]

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[29] Schimpf MO et al. Sling surgery for stress urinary incontinence in women: a systematic review and metaanalysis. Am J Obstet Gynecol. 2014 Jul;211(1):71.e1-71.e27. doi:1.1016/j.ajog.2014.01.030. Epub 2014 Jan 30.

[30] Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction, and American Urogynecologic Society. Position statement on mesh midurethral slings for stress urinary incontinence. 2014. Accessed 3 May 2016. Available from: http://sufuorg.com/docs/news/augs-sufu-mus-position-statementapproved-1-3-2014.aspx

[31] Laurikainen E, et al. Five-year results of a randomized trial comparing retropubic and transobturator midurethral slings for stress incontinence. Eur Urol. 2014; http://dx.doi.org/10.1016/j.eururo.2014.01.031.

[32] Cox A, et al. Surgical management of female SUI. Is there a gold standard? Nat Rev Urol. 2013;10:78-89.

[33] Cresswell J, et al. Long-term evaluation of tension-free vaginal tape (TVT) outcomes for a UK surgeon: Objective assessment and patient satisfaction questionnaires. Br J Med Surg Urol. 2008;1:58-62.

[34] Schimpf MO, et al. Sling surgery for stress urinary incontinence in women: a systematic review and metaanalysis. Am J Obstet Gynecol. Jul 2014;211(1):71.e1-71.e27; Ford AA, et al. (Cochrane Review[FULL]) Mid-urethral sling operations for stress urinary incontinence in women. The Cochrane Library 2015, Issue 7; Tommaselli GA, et al. Medium-term and long-term outcomes following placement of midurethral slings for stress urinary incontinence: a systematic review and metaanalysis. Int Urogynecol J (2015); DOI 10.1007/s00192-015-2645-5; Fusco F, et al, Updated Systematic Review and Meta-analysis of the Comparative Data on Colposuspensions, Pubovaginal slings, and Midurethral tapes in the Surgical Treatment of Female Stress Urinary Incontinence. Eur Urol. 2017 May 4. pii: S0302-2838(17)30334-2. doi: 10.1016/j.eururo.2017.04.026. [Epub ahead of print] PubMed PMID: 28479203.

[35] Moore J, et al. The use of tantalum mesh in cystocele with critical report of ten cases. Am J Obstet Gynecol. 1955; 69:1127-35; Williams TH, TeLinde RW. The Sling Operation for Urinary Incontinence Using Mersilene Ribbon. Obstet Gynecol 1962; 19:241-245; Moir JC. The gauze-hammock operation. J Obstet Gynaecol Br Commonw. 1968; 75:1-9; Morgan JE. A sling operation, using Marlex polypropylene mesh, for treatment of recurrent stress incontinence. Am J Obstet Gynecol. 1970; 106:369-77; Stanton SL. Stress incontinence: why and how operations work. Clin Obstet Gynaecol. 1985; 12:369-77; Stanton SL. Stress incontinence: why and how operations work. Urol Clin North Am. 1985; 12:279-84; Kammerer-Doak DN, et al. Vaginal erosion of cadaveric fascia lata following abdominal sacrocolpopexy and suburethral sling urethropexy. Int Urogynecol J Pelvic Floor Dysfunct. 2002;13(2):106-9; Julian TM. The efficacy of Marlex mesh in the repair of severe, recurrent vaginal prolapse of the anterior midvaginal wall. Am J Obstet Gynecol. 1996;175(6):1472-5; Nicita G. A new operation for genitourinary prolapse. J Urol. 1998;160:741–5; Timmons MC, Addison WA. Mesh erosion after abdominal sacrocolpopexy. J

Pelvic floor surgeons are expected to be familiar with how to implant midurethral slings and should be familiar with complications that can occur with or without mesh.[36]

Looking at reports published in the medical literature and the MAUDE database, Stanford and Paraiso (2008) reported complications related to suburethral sling procedures.[37] They reported on 13,737 cumulative patients the prevalence and overall rates of complications: voiding dysfunction (16.3%), detrusor overactivity (15.4%), urinary retention (14.2%), erosion/extrusion (6.03%), dyspareunia (4.3%), UTI/infections (5.5%), hematoma (2%), pain (7.3%), abdominal and pelvic organ injury (3.3% - 1816 patients), deep vein thrombosis and death (only case reports – no overall incidence). These involve reported events with a denominator of nearly 14,000 patients however over 1 million suburethral sling procedures have been performed worldwide therefore the actual incidence is likely much lower and are influenced by uncontrollable factors (age, obesity, smoking status, chronic disease conditions, prior gynecologic surgery, among other factors).[38] The AUA Position Statement on the use of vaginal

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Pelvic Surg 1997;3:75-80; Iglesia CB, et al. The use of mesh in gynecologic surgery. Int Urogynecol J Pelvic Floor Dysfunct. 1997; 8:105-15; Flood CG, Drutz HP, Waja L. Anterior colporrhaphy reinforced with Marlex mesh for the treatment of cystoceles. Int Urogynecol J Pelvic Floor Dysfunct. 1998;9(4):200-4; Myers DL, LaSala CA. Conservative surgical management of Mersilene mesh suburethral sling erosion. Am J Obstet Gynecol. 1998; 179:1424-8; Kohli N, et al. Mesh erosion after abdominal sacrocolpopexy. Obstet Gynecol. 1998; 92:999-1004; Chaliha C, Stanton SL. Complications of surgery for genuine stress incontinence. Br J Obstet Gynaecol. 1999; 106:1238-45; Schettini M, Fortunato P, Gallucci M. Abdominal sacral colpopexy with prolene mesh. Int Urogynecol J Pelvic Floor Dysfunct. 1999;10(5):295-9; Mage P. Interposition of a synthetic mesh by vaginal approach in the cure of genital prolapse. J Gynecol Obstet Biol Reprod 1999;28:825–9; Migliari R, De angelis M, Madeddu G, Verdacchi T. Tension-free vaginal mesh repair for anterior vaginal wall prolapse. Eur Urol. 2000;38:151–5; Hardiman P, Oyawoye S, Browning J. Cystocele repair using polypropylene mesh. Br J Obstet Gynaecol. 2000;107:825–6; Diana M, Zoppe C, Mastrangeli B. Treatment of vaginal vault prolapse with abdominal sacral colpopexy using prolene mesh. Am J Surg. 2000;179(2):126-8; Weber AM, Walters MD, Piedmonte MR, Ballard LA. Anterior colporrhaphy: a randomized trial of three surgical techniques. Am J Obstet Gynecol. 2001;185:1299–1304; Sand PK, Koduri S, Lobel RW, Winkler HA, Tomezsko J, Culligan PJ, et al. Prospective randomized trial of polyglactin 910 mesh to prevent recurrence of cystoceles and rectoceles. Am J Obstet Gynecol. 2001;184:1357–1362; Kuuva N, Nilsson CG. A nationwide analysis of complications associated with the tension-free vaginal tape (TVT) procedure. Acta Obstet Gynecol Scand. 2002; 81:72-7; Tamussino KF, et al. Austrian Urogynecology Working Group. Tension-free vaginal tape operation: results of the Austrian registry. Obstet Gynecol. 2001; 98(5 Pt 1):732-6; Karram MM, et al. Complications and untoward effects of the tension-free vaginal tape procedure. Obstet Gynecol. 2003; 101(5 Pt 1):929-32; Jelovsek JE, Barber MD, Brubaker L, Norton P, Gantz M, Richter HE, Weidner A, Menefee S, Schaffer J, Pugh N, Meikle S; NICHD Pelvic Floor Disorders Network. Effect of Uterosacral Ligament Suspension vs Sacrospinous Ligament Fixation with or without Perioperative Behavioral Therapy for Pelvic Organ Vaginal Prolapse on Surgical Outcomes and Prolapse Symptoms at 5 Years in the OPTIMAL Randomized Clinical Trial. JAMA. 2018; 319:1554-1565; Adhoute F, Soyeur L, Pariente JL, Le Guillou M, Ferriere JM. Use of transvaginal polypropylene mesh (Gynemesh) for the treatment of pelvic floor disorders in women. Prospective study in 52 patients. Prog Urol. 2004;14:192–6; Shah DK, Paul EM, Rastinehad AR, Eisenberg ER, Badlani GH. Short-term outcome analysis of total pelvic reconstruction with mesh: The vaginal approach. J Urol. 2004;171:261–3

[36] Gormley EA, Kaufman M. National medical student curriculum. American Urological Association, Education & Research (2016); Kenton K, Valaitis S, et al. AUGS education committee: Resident learning objectives. AUGS; The 2012 ABOG and ABU Guidelines to Learning in FPMRS; ACGME. ACGME program requirements for graduate medical education in Female Pelvic Medicine and Reconstructive Surgery (Obstetrics and Gynecology or Urology). 2016;ACOG. Obstetrics and Gynecology Resident Training Requirements. ACOG Division of education.

[37] Stanford EJ, Paraiso MF. A comprehensive review of suburethral sling procedure complications. J Minim Invasive Gynecol. 2008 Mar-Apr;15(2):132-45.

[38] Ala-Nissila S, et al. Tension-free vaginal tape – a suitable procedure for patients with recurrent stress urinary incontinence. Acta Obstet Gynecol. 2010;89:210-6.

mesh for the surgical treatment of SUI states the synthetic slings are an appropriate treatment choice for women with SUI and that the rate of complications is acceptably low.[39]

The follow up AUA Position Statement (2013) reiterated that the utility and safety of TVT are well established:

- Suburethral synthetic polypropylene mesh sling placement is the most common surgery currently performed for SUI. Extensive data exist to support the use of synthetic polypropylene mesh suburethral slings for the treatment of female SUI, with minimal morbidity compared with alternative surgeries. Advantages include shorter operative time/anesthetic need, reduced surgical pain, reduced hospitalization, and reduced voiding dysfunction. Mesh-related complications can occur following polypropylene sling placement, but the rate of these complications is acceptably low. Furthermore, it is important to recognize that many sling-related complications are not unique to mesh surgeries and are known to occur with non-mesh sling procedures as well. It is the AUA's opinion that any restriction of the use of synthetic polypropylene mesh suburethral slings would be a disservice to women who choose surgical correction of SUI. Additionally, both the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) and the AUA support the use of multi-incision monofilament midurethral slings for the treatment of SUI in properly selected patients who are appropriately counseled regarding this surgical procedure by surgeons who are trained in the placement of such devices, as well as the recognition and management of potential complications associated with their use.

- Multiple case series and randomized controlled trials attest to the efficacy of synthetic polypropylene mesh slings at 5-10 years. This efficacy is equivalent or superior to other surgical techniques. There is no significant increase in adverse events observed over this period of follow up. Based on these data, the AUA Guideline for the Surgical Management of Stress Urinary Incontinence concluded that synthetic slings are an appropriate treatment choice for women with stress incontinence, with similar efficacy but less morbidity than conventional non-mesh sling techniques.

IUGA's analysis reports that MUS like the TVT have been shown to be as effective as more invasive traditional surgery with major advantages (utility and desirability) of shorter operating and admission times, and a quicker return to normal activities together with lower rates of complications (IUGA July 2014 Position Statement on Mid-Urethral Slings for Stress Urinary Incontinence). This has resulted in MUS becoming the operation of choice in Europe, Asia, South America, South Africa, Australasia and North America for treatment of SUI with several million procedures performed worldwide.

Most recently, ACOG and AUGS conducted a systematic review of the medical literature and issued Practice Bulletin No. 155 Urinary incontinence in women.[40] The following conclusions and recommendations based on good and consistent (Level A) evidence:

[39] AUA Position Statement on the Use of Vaginal Mesh for the Surgical Treatment of Stress Urinary Incontinence. http://www.fda.gov/MedicalDevices/Safety/A;ertsandNotices/ucm262435.htm.

- Initial midurethral sling surgery results in higher 1-year subjective and objective cure rates than pelvic floor physical therapy in women with stress urinary incontinence.
- Synthetic midurethral slings demonstrate efficacy that is similar to traditional suburethral fascial slings, open colposuspension, and laparoscopic colposuspension. Compared with suburethral fascial slings, fewer adverse events have been reported with synthetic midurethral slings. Voiding dysfunction is more common with open colposuspension than with synthetic midurethral slings.
- There are substantial safety and efficacy data that support the role of synthetic mesh midurethral slings as a primary surgical treatment option for stress urinary incontinence in women.

TVT procedure

As with all anti-incontinence surgeries, the procedure must be learned. The Burch, MMK, and pubovaginal sling require much more time to learn and to perfect compared to the TVT. Learning to harvest rectus fascia or tensor fascia lata or learning to dissect into the retropubic space is difficult and is therefore associated with significant pain and morbidity. Naturally, surgeons looked for a less invasive method consistent with all surgical specialties looking for less invasive methods to perform complex interventions (TAVR, laparoscopic intestinal surgery, radiologic interventions, etc). The design of the TVT allows a small upward passage of anatomically shaped trocars in which the exit site can be sealed with Dermabond or a stitch. It was also desirable to have an anchorless sling unlike prior more invasive procedures that led to pain, voiding problems, osteomyelitis, hematoma, as well as erosions and exposures. Ogah et (2009) performed a metaanalysis and reported that compared to the top-down versus the bottom-up trocar insertion, the TVT method (bottom-up) was associated with fewer bladder perforations (4.7% vs 8.5%), fewer vaginal tape exposures (0.7% vs 3.5%), and higher cure rates (92% vs 97%).[41] (The learning curve is much shorter and repeatable. The IFU clearly describes the steps involved in performing the TVT procedure and the tension-free placement of the 1.1 cm wide polypropylene mesh under the mid-urethra. It is suggested that surgeon experience is a factor in success of the TVT procedure as it is with all surgical interventions.[42]

Cystoscopy is recommended to be performed during the TVT procedure to recognize intraoperative injuries such as bladder or urethral perforation. The incidence and risk of injury is similar to the Burch procedure but much easier to handle. It is suggested that the trocar be withdrawn and replaced. Prolonged bladder drainage with the TVT injury is not required. In my hands, I cannot recall a bladder or urethral injury in several years.

Satisfaction

Several TVT studies have assessed their patients over several years post-operatively and have found that the majority of patients are satisfied with their operative results.[43] [44] [45] In a large

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[40] American College of Obstetricians and Gynecologists. Obstet Gynecol 2015;126:e66–81.

[41] Ogah, J et al. Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women: A short version Cochrane review. Neurouro and Urodyn. 2011;30:284-291.

[42] Withagen MIL, Milani AL. Which factors influenced the result of a tension free vaginal tape operation in a single teaching hospital? Acta Obstetricia et Gynecologica. 2007; 86: 1136-9.

[43] Song PH, et al. The long-term outcomes of the tension-free vaginal tape procedure for treatment of female stress urinary incontinence: Data from minimum 13 years of follow up. LUTS 2017;9:10-14.

Finnish study, satisfaction 5-years following the TVT was 94.2% and following the TVT-O was 91.7%.[46] In a large study of over 500 women, the TVT and TVT-O showed sustained improvement post-operative satisfaction.[47]

Dyspareunia

Vaginal and vulvar pain is relatively prevalent in women. Investigation of the underlying prevalence and incidence of prolonged (≥6 months) and severe dyspareunia in a non-patient population of women revealed that 9.3% of women suffer vaginal or vulvar pain or severe dyspareunia.[48] Schimpf et al (2014) and the 2009 AUA Guidelines reported similar findings of 4-7% incidence of sexual dysfunction following implantation of a retropubic sling; 8% after implantation of a PVS; and 0% following implantation of a synthetic midurethral sling. (see AUA).

De novo detrusor instability

The development of de novo detrusor instability is a known complication of any anti-incontinence surgery. This is also true of the TVT mid-urethral sling and does not represent a defect or design flaw with the device or procedure. It is a fact inherit to all surgical attempts to surgically correct urinary incontinence. Liapis et al (2008) found a 9% incidence at 5-years which increased slightly to 11% at 7-years following a tension-free vaginal tape (TVT) (see Liapis et al 2008). In some patients with urge incontinence (UI) diagnosed preoperatively, the UI may disappear post-operatively yet may develop de novo in others. Olsson et al (2010) diagnosed UI in 19.5% (24/123) pre-operatively and reported that is disappeared in 13 of those 24 patients post-operatively and remained unchanged in 11 after TVT. However, de novo urge incontinence appeared in 21.2% (21/99) post-operatively.[49] Up to 20% of patients may develop de novo urge incontinence in the post-operative period and in some of those it may decrease overtime (see Ala-Nissila et al 2010).

Inflammatory reaction

Plaintiff's experts state that mesh creates a chronic inflammatory reaction. It is important to understand that a foreign body reaction is anticipated and expected after placement of the polypropylene mesh. From a clinical perspective, it is anticipated that a foreign body reaction will occur and that the long-term result will be durable support at key anatomic locations. After the mesh is implanted, macrophages infiltrate the area and this leads to the deposition of collagen over approximately a 10-14 day period. This is the anticipated tissue reaction. When Amid type 3 mesh was employed (much like any other more solid structure), the tissue inflammation is prolonged and can lead to pseudocapsulation. To apply this description to type 1 macroporous,

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[44] Li B, et al. Long-term Outcomes of the Tension-Free Vaginal Tape Procedure for Female Stress Urinary Incontinence: 7-Year Follow-up in China. J Min Invas Gyn.(2012);19:201–205.

[45] Svenningsen R et al. Long-term follow-up of the retropubic tension-free vaginal tape procedure. Int Urogynecol J 2013;24:1271-8.

[46] Laurikainen E, et al. Eur Urol. 2014; http://dx.doi.org/10.1016/j.eururo.2014.01.031.

[47] Kenton K, et al. 5-year longitudinal followup after retropubic and transobturator mid urethral slings. J Urol. 2015;193:203-10.

[48] Danielsson, I et al. Prevalence and incidence of prolonged and severe dyspareunia in women: results from a population study. Scand J Pub Health. 2003;https://doiorg/10.1080/14034940210134040.

[49] Olsson A, et al. Long-term efficacy of the tension-free vaginal tape procedure for the treatment of urinary incontinence: A retrospective follow-up 11.5 years post-operatively. Int Urogynecol J (2010) 21:679–683.

knitted mesh is not clinically accurate. The TVT polypropylene is considered a Amid type 1 mesh which by definition has a pore size of > 75 µ. The normal healing response following surgery requires macrophage infiltration into the wound area with subsequent collagen deposition. Macrophages are approximately 16-20 µ which is much smaller than the TVT mesh pore size even partially distorted pores. The pore size of TVT is approximately 1,379 microns (Moalli 2008). The known anti-inflammatory reaction or foreign body reaction leads to the desired and expected formation of collagen support and is not a damaging process in the vast majority of patients. (Falconer et al. 2001).

Infection

Mesh infection is not common after TVT. Culligan et al (2005) reported that the surgical preparation or cleaning of the vagina for pelvic surgery does not sterilize the vagina. Of 31 patients studied, all had a positive vaginal swab culture showing normal vaginal flora.[50] Therefore, any vaginal surgery will be associated with a clean contaminated (class 2) environment of normal vaginal flora which are susceptible to routine antibiotics used prophylactically at surgery. Several plaintiff's expert have impugned the TVT mesh as a cause of prolonged infection. This is not supported by existing medical literature. Similar to later study by Stanford and Paraiso (2008), Sergent et al (2003)[51] found a 7% incidence of UTIs associated with TVT which should be translated to mean that UTIs are not increased following the TVT procedure because UTI following pelvic and abdominal surgery occurs at approximately the same baseline incidence.

Voiding dysfunction

Prolonged voiding occurs after all pelvic reconstructive procedures including midurethral slings. It is common sense when one considers the mechanism responsible for controlling incontinence following the placement of the TVT sling that some women will encounter a change in the voiding habits. Svenningsen et al (2013) have found that following a TVT procedure, minor voiding difficulties are reported such as slow stream and intermittency.[52] The incidence is 6% following needle suspensions, 13% after sling procedures, and 12.5% following colposuspensions. Delayed voiding or retention occurs in approximately 7% following a TVT procedure. The occurrence with all types of bladder and urethral support procedures implicates the inherent qualities of the procedures and does not reflect any design defect with the TVT.[53] [54]

Urodynamic testing is not mandatory and may not be cost effective in some patients prior to performing an anti-incontinence surgery although it is suggested under certain circumstances.[55]

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[50] Culligan PJ et al. A randomized trial that compared povidone iodine and chlorhexidine as antiseptics for vaginal hysterectomy. Am J Obstet Gynecol. 2005 Feb;192(2):422-5.
[51] Sergent F, et al. Pre- and postoperative complications of TVT (tension-free vaginal tape). Prog Urol. 2003 Sep;13(4):648-55.
[52] Svenningsen R, et al. Long-term follow-up of the retropubic tension-free vaginal tape procedure. Int Urogynecol J (2013) 24:1271-8.
[53] Bombieri L, Freeman RM. The management of voiding difficulty after incontinence surgery. The Obstetrician & Gynecologist. 2003;5:66-71.
[54] Ward K, Hilton P. Prospective multicenter randomized trial of tension-free vaginal tape and colposuspension as primary treatment for stress incontinence. BMJ. 2002;325:67-70.
[55] ACOG Committee Opinion 603 June 2014 (reaffirmed 2017).

[56] However, pre-operative workup with uroflowmetry and pressure-flow studies may suggest situations when obstruction may be more likely to occur. For example, a peak flow rate of less than 15 mL/s, residual volumes greater than 100 mL, or detrusor contraction of less than 15-20 cm H2O may arbitrarily point to poor detrusor function putting the patient at risk of retention (see Bombieri and Freeman 2003).

It should be noted that the TVT has also been found to be a successful surgery in some conditions involving underlying voiding dysfunction. For example, in a condition called intrinsic sphincteric deficiency (ISD) in which the urethra lacks sufficient internal pressure to hold urine, the TVT shows therapeutic success of 82%.[57] As well, the tension-free vaginal tape (TVT) is a good choice for women suffering from voiding dysfunction secondary to neuropathic bladder.[58]

Repeat Sling

It is clearly understood that not all patients with be continent following their TVT procedure. The question of how to handle these patients can be perplexing. Riachi et al (2002) reported rather early on patients with a failed initial TVT procedure.[59] They reported that a repeat TVT pubovaginal sling for the treatment of patients with recurrent stress urinary incontinence was feasible and safe. Two patients underwent repeat TVT slings performed between 6 and 9 months following the initial procedure without revision or removal of the previous TVT sling. Both patients reported surgical cure without significant intraoperative or postoperative complications. It is now the standard of care to consider a repeat TVT after an initial failed TVT.[60]

Pain

Pain is a relatively common occurrence in women in general. First, pain is associated with any and all surgeries to varying degrees and is usually self-limiting. In the general population, Latthe P (2006) found that dysmenorrhea affect 17-81% of women, dyspareunia 8-22%, and non-cyclical pain 2.1-24%.[61] From clinical experience, most surgeons do not take into consideration complaints of pain such as dysmenorrhea or dyspareunia prior to surgery. However, studies have looked at pain following the TVT. Several plaintiff's experts have claimed that many patients suffer chronic pain following the placement of suburethral mesh. They contend that when mesh is inserted in the female body it creates a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities. One plaintiff's expert contends that the nerve is drawn to the implanted mesh and is entrapped. I would agree that placement near to a nerve will cause pain. The published medical literature does not support this generalized claim that a large number of

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[56] Geisler JP. Cost-effectiveness of urodynamics testing in women with predominant stress incontinence symptoms. Obstet Gynecol 2014;123(5 suppl):197S.

[57] Wlazlak E et al. Role of intrinsic sphincter deficiency with and without urethral hypomobility on the outcome of tape insertion. Neurourol Urodyn. 2017 Sep;36(7):1910-1916.

[58] Abdul-Rahman A, et al. Long-term outcome of tension-free vaginal tape for treating stress incontinence in women with neuropathic bladders. BJUInt 2010;106:827-30.

[59] Riachi L1, Kohli N, Miklos J. Repeat tension-free transvaginal tape (TVT) sling for the treatment of recurrent stress urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct. 2002;13(2):133-5.

[60] Palva K1, Nilsson CG. Effectiveness of the TVT procedure as a repeat mid-urethra operation for treatment of stress incontinence. Int Urogynecol J Pelvic Floor Dysfunct. 2009 Jul;20(7):769-74. doi: 10.1007/s00192-009-0849-2. Epub 2009 Mar 10.

[61] Latthe P. WHO systematic review of prevalence of chronic pelvic pain: a neglected reproductive health morbidity. BMC Public Health 2006, 6:177.

patients suffer postoperative pain. In fact, a large randomized Austrian study found that a small number of patients reported pain after their TVT (1.4%) or TVT-O (2.7%). There was no statistical difference between these two groups.[62] In my vast clinical experience and as an expert in pelvic pain with numerous peer-reviewed publications in that area, pain following a TVT is nearly always short-term and can be treated conservatively. Often, trigger point injections are useful if pain persists a few weeks following surgery and rarely, mesh excision is required. Most women do not realize the mesh is present and have no associated pain or similar complaints.

Extrusion/erosion

It is unlikely that any topic surrounding vaginal mesh has gotten more attention than the risk of mesh exposure. It is proposed that mesh exposure is more likely if dissection of the vaginal epithelium is not deep enough or full-thickness or if a hematoma develops. It is imperative to understand that erosion is not unique to polypropylene mesh. Amundsen et al (2003) reported erosion following pubovaginal sling procedures that involved autologous tissue harvested from the patient.[63] Further, post implant exposure has been seen with biologic grafts, commonly used sutures, and synthetic materials used in traditional endoscopic Stamey repairs. For example, following a sacrospinous ligament suspension to suspend the apical vagina, permanent suture is found to be exposed relatively often and it is treated conservatively with no long-term sequelae.[64] In essence, there is a possibility of exposure regardless of the material used. In my extensive experience having performed all of the traditional anti-incontinence surgeries except to artificial sphincters, I have seen exposures occur. The incidence with polypropylene mesh commonly used in mid-urethral slings is not associated with high rates of exposure and exposure does not indicate as device or design defect of the TVT.

There was a period of time when unsatisfactory mesh types were placed. These included microporous, multifilament, and/or pressed mesh which were removed from the market. They were classified as Amid type 3 meshes based on hernia mesh classifications. The mesh used in the tension-free vaginal tape (TVT, TVT-O) is a type 1 (Amid classification) which is macroporous, monofilament, polypropylene, knitted mesh.[65] [66]

There is no support in the medical literature that a lighter weight, larger pore, partially absorbable mesh, would be as efficacious and safer than TVT, or that it would eliminate the potential risks, such as mesh exposure.

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[62] Tammaa A, et al for the Austrian Urogynecology Working Group. Retropubic versus transobturator tension-free vaginal tape (TVT vs TVT-O): Five-year results of the Austrian randomized trial. Neurourology and Urodynamics. 2017;9999:1–8.

[63] Amundsen CL et al. urethral erosion after synthetic and non-synthetic pubovaginal slings: Differences in management and continence outcome. J Urol. 2003 July;170:134-7.

[64] Toglia MR, Fagan MJ. Suture erosion rates and long-term surgical outcomes in patients undergoing sacrospinous ligament suspension with braided polyester suture. Am J Obstet Gynecol. 2008 (May);198:600.e1-600.e4.

[65] Amid PK. Classification fo biomaterials and their related complications in abdominal wall hernia surgery. Hernia 1:15-21.

[66] Prien-Larsen J C, Hemmingsen L. Long-term outcomes of TVT and IVS operations for treatment of female stress urinary incontinence: monofilament vs. multifilament polypropylene tape. Int Urogynecol J. 2009;20:703-9.

In a large randomized study reported in an Austrian registry, mesh exposure was seen in 5.2% following a TVT and 4.5% after a TVT-O.[67] This is similar to the 6% reported by Stanford and Paraiso (2008) in the literature review involving almost 14,000 patients. Certainly, lower rates have also been reported. For example, Hyun et al 2009 reported only 6 or 306 patients (1.9%) after TVT.[68] The 2015 Ford Cochrane Review and the FDA 2013 statement on midurethral slings describes an exposure rate of approximately 2%.

Most experienced surgeons who have placed and managed large numbers of TVT patients will attest that management is usually conservative and the vast majority do not require surgical intervention.[69] [70] [71] The incidence of re-operation for vaginal exposure is less than 1%.[72] [73]

It should be stressed that mesh erosion is a known complication of TVT procedures and does not indicate a design or device defect. Several plaintiff's experts claim that mesh commonly erodes into the bladder and urethra. While intravesical mesh exposure is a known complication,[74] it most likely is associated with surgical technique in which the mesh was placed very close to the bladder or urethra or was not recognized at cystourethroscopy. The published incidence of reoperation following TVT for urethral exposure is less than 1 per thousand (see Nguyen et al 2012). Since this phenomenon is known to occur with all anti-incontinence surgery, it is not unique to the TVT and is not indicative of a product defect. Further, the cumulative risk of sling revision or removal usually occurs initially and plateaus within 3 years and then decreases overtime.[75] [76] [77] There are some circumstances in which the odds of experiencing mesh exposure is significantly higher such as with smokers (OR 4.4).[78] Other risk factors for mesh exposure

[67] Tammaa A, et al for the Austrian Urogynecology Working Group. Retropubic versus transobturator tension-free vaginal tape (TVT vs TVT-O): Five-year results of the Austrian randomized trial. Neurourology and Urodynamics. 2017;9999:1–8.
[68] Hyun CH, et al. Seven-year outcomes of the TVT procedure for treatment of female stress urinary incontinence. J Urol. 2009;181(4):Suppl 544.
[69] Kuuva N, Nilsson G. Long-term results of the tension-free vaginal tape operation in an unselected group of 129 stress incontinent women. Acta Obstet Gynecol. 2006;85:482-7.
[70] Svenningsen R, et al. Long-term follow-up of the retropubic tension-free vaginal tape procedure. Int Urogynecol J (2013) 24:1271–1278.
[71] Trabuco EM, et al. Midurethral Slings for the Treatment of Stress Urinary Incontinence: Long-Term Follow-up. Obstet Gynecol. May 2014;123(5):197S
[727272] Nguyen et al Perioperative Complications and Reoperations after Incontinence and Prolapse Surgeries Using Prosthetic Implants Obstet Gynecol 2012;119(3):539-46.
[73] Abdel-Fattah M, et al. Long-term outcomes of transobturator tension-free vaginal tapes as secondary continence procedures. World J Urol. 2017;35:1141-48.
[74] Ward K l, Hilton P. Multicentre randomised trial of tension-free vaginal tape and colposuspension for primary urodynamic stress incontinence: Five year follow up. Neuro Uro. 2006;25(6):568.
[75] Jonsson Funk M et al. Sling revision/removal for mesh erosion and urinary retention: Long-term risk and predictors. Am J Obstet Gynecol. 2013 Jan;28(1):73.e1-73.e7.
[76] Welk B, Removal or Revision of Vaginal Mesh used for the Treatment of Stress Urinary Incontinence. JAMA Surg (2015) Doi:10.1001/jamasurg.2015.2590
[77] Unger C, Indications and risk factors for midurethral sling revision. Int Urogynecol J 2015; DOI:10.1007/s00192-015-2769-7.
[78] Lowman JK, Woodman PJ, Nosti PA, et al. Tobacco use is a risk factor for mesh erosion after abdominal sacral colpoperineopexy. Am J Obstet Gynecol 2008;198:561.e1-561.e4.

have been described, such as older age, atrophy, diabetes mellitus, smoking, and larger vaginal and recurrent vaginal incisions.[79]

Risks factors associated with TVT failure

Known risk factors associated with objective and subjective failure following a TVT have been studied. These affect patient selection and informed consent. Not all studies agree on a standard list of risk factors however published lists include: concurrent prolapse surgery, preoperative anticholinergics, increased age (independent factor), BMI > 25, mixed incontinence, previous continence surgery, ISD, diabetes mellitus, antidepressant/anxiolytic drugs, and respiratory disease.[80] [81]

Mesh migration

Clinically, from a surgical standpoint, migration refers to movement of the mesh usually locally. It has been shown that with the TVT, a very small amount of movement can occur but it does not occur in the vast majority of patients.[82] Movement of the TVT mesh is usually avoided by proper dissection under the urethra without extension of the incision to the vagina. Erosion is uncommon and whether it occurs due to the normal repair functions of the body or as a result of improper placement is not clearly understood but it is likely a combination of factors.

The general comment that mesh migrates is debatable and several researchers have shown that mesh, particularly TVT mesh, does not migrate. Plaintiff's experts opine that the devices are designed to correct anatomical position of the organs, therefore are designed to press against the organs. This pressure can force the mesh to migrate into the organs. In other words, the presents of the mesh near an organ such as the bladder which fills and empties causes friction and the mesh wears down the anatomic layers and becomes exposed. I cannot completely disagree that this is a possible mechanism. However, from a clinical standpoint, proper dissection of the vaginal epithelium and placement of the mesh in the proper location should not and in the vast majority of patients, does not lead to any organ damage.

Polypropylene degradation

Plaintiff's experts state that polypropylene degrades, becomes brittle, and cracks in vivo. From a clinical perspective, I am not aware of any publications that the TVT mesh cracks or loses support. It is true that some patients have recurrent SUI or POP and that mesh implants can fail to control continence or prolapse but there is no evidence that this occurs due to brittleness. In fact, Thames et al (2017) have shown that the microscopic visualization of a cracked surface is the effect of the formalin-protein fixation process, and not in vivo degradation.[83] At most, what other studies have suggested is that over time some surface degradation may occur but the support matrix is clinically preserved. Multiple long-term studies at 17-year follow-up from

[79] Kokanali, Risk factors for mesh erosion after vaginal sling procedures for urinary incontinence. Eur J Obstet Gynecol 2014; 177: 146-150.
[80] Barber D et al. Risk factors associated with failure 1 year after retropubic or transobturator midurethral slings. Am J Obstet Gynecol. 2008 Dec;199(6):666.e1-7.
[81] Lorenzo-Gomez MF et al. Risk factors ffailure after transobturator vaginal tape for urinary incontinence. Actas Urol Esp. 2011 Sep;35(8):454-8.
[82] Dietz HP, et al. Does the tension free vaginal tape stay where you put it? Am J Obstet Gynecol. 188: 950–953, 2003.
[83] Thames SF et al. The myth: In-vivo degradation of polypropylene meshes. Int Urogynecol J. 2017;28:285-97.

Nilsson (2013), Braga (2018), and Bakas (2018) have demonstrated the clinical durability of the TVT with no significant long-term concerns.

Even if a finite amount of degradation occurred it would not render the polypropylene less functional. From a clinical perspective, I am not aware of any publications that the TVT mesh degrades or loses support. It is true that some patients have recurrent SUI or POP and that the mesh implant can fail but there is no evidence that this occurs due to degradation. At most, over time, if some surface degradation does occur the support matrix is clinically preserved and the support scaffold is preserved. I offer a clinical analogy. One can see that the surface of the steel beam of a bridge degrades over time however the strength of the scaffold is largely preserved and generally considered safe. It is the goal of using implant materials that they incorporate into the tissues through the normal healing response and create additional support that did not exist prior to surgery.

Cytotoxicity

Plaintiff's experts have drawn conclusions rodent studies in which polypropylene sheets were implanted and some of the rodents developed sarcomas that polypropylene mesh is cytotoxic. In a very large study looking at over 5 million women, the cancer risk following a sling procedure is no different than non-operated patients.[84]

Mesh contracture/shrinkage

It is important to understand that the mesh fibers themselves do not shrink; rather, it is the wound or damaged tissue surrounding the implant which undergoes normal wound contraction that causes a reduction in the surface area due to retraction of the fibrotic scar tissue in and around the mesh implant. Plaintiffs' expert has suggested that all polypropylene meshes will contract in variable amounts, reportedly between 20 -50 % or more of the original surface area. The contraction tightens the mesh devices and leads to tissue and organ damage. He also writes that one of the clinical manifestations of mesh tightening by contraction is the mechanism for urinary outflow obstruction.

What is being described is the normal and anticipated healing process. Historically, native tissue vaginal support and anti-incontinence surgeries were found to have comparably poor long-term results.[85] The adaptation of using foreign body materials such as polypropylene mesh has brought about improved long-term results for patients suffering from SUI.[86] [87] These opinions are not consistent with the existing TVT mesh mid-urethral sling clinical literature. Although, shrinkage is postulated, a well-designed clinical study using sophisticated ultrasonic data (see Dietz et al) reporting that there is no TVT mesh shrinkage. There are no clinical publications

[84] Altman D et al. Cancer risk after midurethral sling surgery using polypropylene mesh. Obstet Gynecol. 2018 Mar;131(3):469-74.
[85] Stanford, E. J., Cassidenti, A., & Moen, M. D. (2012). Traditional native tissue versus mesh-augmented pelvic organ prolapse repairs: providing an accurate interpretation of current literature. Int Urogynecol J, 23(1), 19-28.
[86] Jelovsek JE, et al. Randomised trial of laparoscopic Burch colposuspension versus tension-free vaginal tape: long-term follow up. BJOG. 2008;115:209-25.
[87] Liapis A, Bakas P, Creatsas G. Long-term efficacy of tension-free vaginal tape in the management of stress urinary incontinence in women: efficacy at 5- and 7-year follow-up. Int Urogynecol J Pelvic Floor Dysfunct 2008;19:1509-12.

that I am aware of showing shrinkage causes urinary obstruction or organ damage as a direct result.

It is proposed that polypropylene mesh contracts and shrinks (perhaps 30%) leading to complications however 30% would not be of clinically consequence. The TVT mesh width is 1 cm at the time of implantation. If there is a 30% reduction in width, this would not be clinically significant. I support this by pointing out that a continence zone of the female urethra was described in 1974.[88] The ICS Terminology Committee describes the functional urethral length (FUL) which is about 2 cm in the normal female urethra.[89] During complex urodynamic testing (UD), withdrawing the urethra pressure catheter device locates the maximum urethral closure pressure (MUCP) at approximately the mid-urethra. Additionally, the leak point pressure (LPP) which is the precise pressure at which urinary leakage occurs is routinely measured during complex UD testing. Recent techniques have used the APIR (abdominal to urethral impact ratio).[90] Therefore, it has been known for greater than 40 years that the mid-urethra contains an area of increased resistance (intravesical pressure < urethral pressure) which provides women with continence under normal situations. It is known that the TVT provides increased resistance against urethral dilation at rest and with straining. If there is a 30% reduction in mesh width, which is debatable, it is not of clinical significance. Ultrasound studies evaluating TVT at 1.6 and 3 year follow up found no clinically significant shrinkage or contraction of the TVT.[91] [92] Similar findings were noted in Nilsson's 17 year follow-up.[93]

Biofilm formation/infection

Plaintiff's experts propose that polypropylene meshes are invariably associated with a chronic inflammatory response which creates the background capable of lowering the pain sensitivity threshold. Dr. Klinge describes this as the mesh-scar complex. He states that it its compartmentalizing in nature, forms attachments to the surrounding tissues creating a risk of compression as a result of external forces, as well as from increased interstitial fluid pressure within the compartments, creates a scar connection to the surrounding tissue leading to distortion and pulling during movements, and that mesh shrinking during scar contraction leads to static tension within and between the attached tissues.

From a clinical point of view and in my expertise as a pelvic surgeon, these observations are not clinically supported phenomena. Clearly, the healing mechanism is variable between patients. However, the rate of pain following mesh implantation is very low particularly after TVT implantation. In fact, the vast majority of patients with mesh, particularly TVT mesh, do not

[88] Gleason et al The Urethral Continence Zone and its relations to incontinence. J Urol 1974 July;112:81-5.
[89] Haylen BT et al. IUGA/ICS joint report on the terminology for female pelvic floor dysfunction. Standardisation and terminology committees IUGA and ICS, joint IUGA/ICS working group on female terminology. 2010;29(1):4-20.
[90] Saaby ML. The urethral closure function in continent and stress urinary incontinent women assessed by urethral pressure reflectometry. Dan Med J. 2014 Feb;61(2):B4795.
[91] Dietz HP et al, Dietz HP, et al. [Pop 68, median 1.6 yrs fu] Does the Tension-Free Vaginal tape stay Where you Put It? Am J Obstet Gynecol 2003; 188: 950-3
[92] Lo TS, et al. Ultrasound assessment of mid-urethra tape at three-year follow-up after tension-free vaginal tape procedure. Urology 2004; 63: 671-675.
[93] Nilsson CG, et al, Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence. Int Urogynecol J (2013) 24: 1265-1269

suffer post mesh implantation pain and most to do not realize the mesh is present. The mechanisms associated with chronic pain are well described. It is true that chronic irritation can result in spinal up-regulation however, there is no clinical data to my knowledge, that supports the claim that mesh alone causes chronic nerve irritation or damage when it is properly placed. In my clinical expert opinion, these do not offer support that TVT mesh shrinks or contracts to any clinically relevant degree and is it direct contrast to a study by Dietz et al (2011).[94]

Plaintiff's experts propose that a biofilm forms around the polypropylene mesh stating that the vagina is considered a "clean contaminated" field. Indeed, it is a clean contaminated surgical field (class 2). The implantation of mesh may result in a biofilm which will make it difficult for the host cells to kill the mesh infection; in fact, the development of these biofilms will protect the harmful bacteria that the host cells set out to kill.[95] [96] [97] I am not aware of any clinical publications supporting this claim that implanted polypropylene mesh is chronically contaminated or chronically infected or that a biofilm forms around the mesh.

IFU

The manufacturer's tension-free vaginal tape (TVT) products provide general guidelines and instructions about the basic steps to be used when implanting the device. The general indications and contraindications are listed. The surgical techniques and contraindications are important basic medical information that all surgeons should apply when using the device in question. However, they are not inclusive nor do they include all of the possible complications associated with the performance of a midurethral sling whether mesh is used or not. The IFU does not ensure surgeon competency or preclude variations in the technique used by the surgeon to fit the specific needs of any particular patient. Pelvic floor surgeons are expected to be aware of the usual risks associated with the procedure they are performing based on their education, training, clinical experience, peer discussions, knowledge obtained from attending conferences, and ongoing reviews of the medical literature. The IFU is not intended to provide further education and surgeons are not taught to rely on IFUs to become familiar with the risks of pelvic floor surgery with or without mesh. Board-certified surgeons do not necessarily need to be aware of the contents of the IFU given their level of expected knowledge of the frequency and severity of risks that they acquire from their clinical experience, education and ongoing review of the medical literature. The IFUs are not missing risks that pelvic floor surgeons would already be expected to know. Ethicon provided additional information about risks through professional education sessions, cadaver labs, didactic sessions, slide decks, and Resource Monographs. Pelvic floor surgeons do not rely on IFUs. Rather, they obtain their knowledge of risks from other sources.

Plaintiff's expert Dr. Pence offers a large list of complications listed in the IFU: pain (including chronic pain), infection, abscess, wound sinus, seroma, hematoma, hemorrhage, venous thrombosis, vaginal perforation, vaginal scarring, foreign body reaction, delayed healing, shrinkage, due to contraction and scarring, urethral injury, voiding dysfunction, de novo detrusor instability or urgency, urinary retention, urinary tract infection, dysuria, hematuria, worsening or

[94] Dietz HP et al. Mesh contraction: myth or reality? Am J Obstetrics Gynecol. 2011 Feb;204(2):173.e1-4.
[95] Osterberg B. ActaChirScand1979;145:431.
[96] Merritt K. J BiomatAppl 1991;5:185.
[97] An Y. J Biomed Mater Res (Appl Biomat) 1998;43:338.

recurrence of incontinence, de novo dyspareunia, complications requiring mesh removal and/or re-operation, device failure, death.

It should be clearly understood that all of these complications exist in non-mesh surgery as well. In lieu of mesh exposure in non-mesh bladder neck suspensions and sub-urethral slings, exposure of suture material and other support materials are known complications. All of the complications listed by Dr. Pence are potential complications in non-mesh pelvic surgeries. ***The informed consent and risk and benefits discussions are no different yet no IFU is necessary.*** Peggy Pence neglects to consider how pelvic floor surgeons were able to counsel patients about risks of chronic pain, dyspareunia, failure, etc., prior to performing native tissue repairs which doesn't come with an IFU. I reiterate my statements above that the manufacturer's IFU provides general guidelines and instructions about the basic steps to be used when implanting the device. It is not a requirement that the surgeon memorizes or follows the IFU or subsequent changes to the IFU. It is a regulatory requirement that an IFUs exist. They cannot realistically include all the possible complications associated with the performance of a midurethral sling whether mesh is used or not despite arguments to the contrary. The IFU does not, cannot, and should not ensure surgeon competency or preclude variations in the technique used by the surgeon to fit the specific needs of any particular patient. The IFU is not intended to provide further education and the surgeon does not necessarily need to be aware of the contents of the IFU. The physician should use their surgical experience and judgment to determine if polypropylene mesh is appropriate for their patients. A recent survey by Faber et al. (2017) supports the lack of reliance by urologists on the IFU. It most likely would not have changed the decision by the patient to receive the implant particularly since the risk of complications is relatively low and shares the same complications of older, non-mesh methods. The IFU's content would not change the surgeon's decision or the plaintiff's presumed injuries. Peggy Pence fails to consider all of the sources where surgeons obtain risk information and the lack of reliance on information in the IFU. The weight Peggy Pence places on the IFU is not consistent with real world learning, teaching, or clinical practice.

Summary

Knowing the history of the poor relative success rates as well as the complications and more invasive nature of traditional anti-incontinence surgeries, it is easy to understand how and why the TVT mid-urethral sling became the preferred and universally recommended surgical approach. The procedure has been compared to many other surgeries and it has shown equal or superior long-term results.

The TVT has been more extensively studied than any other incontinence surgery and despite known complications, it is regarded as safe and effective by all of the major medical and surgical societies worldwide. The design of the device has proven to be safe and allegations of defective design is in no way consistent with the international adoption, long-term results, high patient satisfaction, and recommendation that it is the preferred surgical method by leading medical and surgical societies.

The alleged design defect claims against TVT are not supported by reliable clinical studies acknowledging their in vivo occurrence or any resulting clinical significance. These design defect theories are refuted by the highest level of scientific evidence demonstrating the safety

and efficacy of TVT. There is also no reliable scientific evidence that a theoretical device with less mesh or larger pores suggested by plaintiffs' experts would be as efficacious and safer than TVT.

The TVT IFU and educational materials are undoubtedly sufficient for their purpose. Surgeons do not rely on them for most of their knowledge or education about performing the procedure. Therefore, accusations that the IFU or educational materials are misleading or should have gone beyond the standard recommendations set forth by existing regulations is non-sensical. It is a double standard to require a simple, well designed, and extensively studied technique like the TVT be required to have an unrealistically robust or complete IFU when the surgeon can perform a much more dangerous and invasive procedure such as the Burch or pubovaginal sling with fascial harvesting and no such requirement for educational materials exist.

The TVT and its iterations has revolutionized the treatment of female SUI, ISD, neurogenic bladder, and mixed incontinence. The complications, albeit at times devastating, do not affect the vast majority of patients and are considerably less than traditional surgical methods. It is my expert opinion that the TVT polypropylene mid-urethral mesh and similar forms of suburethral mesh procedures are the gold standard in treating female urinary incontinence.

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Edward Stanford MD
September 28, 2018

Edward Stanford

General Reliance List
in Addition to Materials Referenced in Report

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Production Materials

Document Description [Bates Range]
000001_4275674_d_Use of Gynemesh PS in Prolapse Surgery Power Point
2000 TVT Surgeon Monograph
2001 TVT Surgeon's Monograph
2003 Gynemesh PS Early Clinical Experience White Paper
2003 Gynemesh PS white paper. Gynemesh PS Early Clinical Experience.
2004 Gynemesh PS Study Poster - AUGS 2004 San Diego. Lucente V, Hale D, Miller D, Madigan J. A Clinical Assessment of Gynemesh PS for the Repair of Pelvic Organ Prolapse.
2007 Prolift Prof Ed Slides
Clinical Evaluation Report - Gynemesh PS by Piet Hinoul - April 26, 2013
ETH.MESH.00012009-089 - TVM Prospective Data (French Trial) - Exhibit 522
ETH.MESH.00013529-534 - Prolift+M IFU
ETH.MESH.00018382 - Powerpoint GYNECARE GYNEMESH* PS Nonabsorbable PROLENE* Soft Mesh in the Treatment of Pelvic Organ Prolapse
ETH.MESH.00159266-369 - Gynemesh PS, Prolene Soft Mesh in the treatment of POP – Pelvic Floor Surgery and Anatomic Dissection Lab
ETH.MESH.00167104 - 2006 TVT Laser Cut Clinical Expert Report
ETH.MESH.00295355 (TVTE-338-10-7.12) - 2010 TVT-Exact Prof Ed
ETH.MESH.00308094 (2629_2006-07-12) - 2006 TVT-Secur
ETH.MESH.00354732 (TVTA-088-11-2.13) - 2011 TVT-Abbrevo
ETH.MESH.00369995 (2008-570) - 2008 TVT Family of Products Prof Ed
ETH.MESH.00369999 (2008-135) - 2008 TVT-Secur
ETH.MESH.00370421 (TVTO_0113-09-8.11) - TVT-O FDA Public Health Notice
ETH.MESH.00373310 (2003-712) - 2003 TVT Prof Ed
ETH.MESH.00393045-46 (2008-582) TVT-O Procedural Steps
ETH.MESH.00394849 - Gynemesh PS Panel Powerpoint - Drs. Robinson, Miller, Winkler, England
ETH.MESH.00395374-380 - 2001 June 22; Scientific Advisory Chicago Meeting re POP mesh includes Prolene Soft
ETH.MESH.00397674 (2002-275) - 2002 Minimizing & Managing TVT Complications Prof Ed
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